

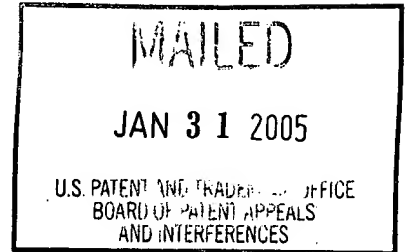
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DOUGLAS H. ROBINSON

Appeal No. 2004-2077
Application No. 09/759,345

ON BRIEF



Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we remand the application to the examiner to consider the following issues and to take appropriate action.

Claims 1-29 are pending in the application. Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for producing a bacterium that contains a eukaryotic and/or viral gene, which comprises culturing virally-infected eukaryotic cells under low oxygen conditions to produce a bacterium containing a eukaryotic and/or viral gene.

We note appellant's reference to amendments filed concurrently with the Brief. See Brief, pages 8 and 21. The amendments, however, were not entered

into the record. See Answer, page 2, and Brief, page 2, the "amendments have not been entered."

The examiner does not rely on prior art.

GROUND OF REJECTION

1. Claims 1-29 stand rejected under 35 U.S.C. § 101, as the claimed invention is inoperative.
2. Claims 1-29 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.
3. Claims 1 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "under low oxygen conditions."
4. Claims 1-29 stand rejected under 35 U.S.C. § 112, second paragraph, "as failing to set forth the subject matter which appellant[] regard[s] as their [sic] invention."
5. Claims 2, 3 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "subjecting the cells to an aerobic culturing step."
6. Claims 24 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "derived."
7. Claims 24 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "evolved."
8. Claims 24 and 25 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the term "pleiomorphic cell."
9. Claims 27 and 29 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of the phrase "morphology that is neither prokaryotic nor eukaryotic."
10. Claims 24-19 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

DISCUSSION

1. Is a deposit required?

According to the examiner (Answer, page 6), “[t]he invention appears to employ novel strains of Staphylococcus [sic] and Micrococcus. It’s not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of the invention.” Regarding the public availability of starting materials, the examiner finds (Answer, page 16), “[t]he porcine cerebral microvascular endothelial cells are listed as being held by Applicant.”

The examiner, however, failed to identify to which claim, if any, these comments are directed. Further, upon review of the claims on appeal we were unable to identify a single claim that required a specific cell line. See also Brief, page 14, “none of the claims recite specific bacterial isolates....” Accordingly, it appears that the examiner’s comments are in the form of an objection to the specification, rather than a claim rejection. As such, this objection is a petitionable matter, and therefore is not properly before us on appeal.

2. Obviousness-type Double Patenting:

We recognize appellant’s statement (Brief page 8), there is no dispute with regard to the “non-statutory double patenting rejection” as set forth in the Final Office Action, mailed September 23, 2002. It appears that appellant is of the impression that an obviousness-type double patenting rejection should be affirmed on this record. Appellant’s statement, however, raises two questions:

(A) was this rejection withdrawn in the Answer, and if not (B) are all claims on appeal disposed of by affirming this rejection?

A. Was this rejection withdrawn in the Answer?

An obviousness-type double patenting rejection was maintained in the Final Office Action, mailed September 23, 2002. See Final Office Action, pages 3-4. The Answer, however, is silent with regard to this rejection. Accordingly, it appears that this rejection has been withdrawn as a matter of standard procedure. Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 663, 231 USPQ 649, 651-652 (Fed. Cir. 1986).

Accordingly, we remand the application to the examiner to determine whether the obviousness-type double patenting rejection should have been withdrawn from the record. In the event the examiner finds that this rejection should not have been withdrawn, we encourage the examiner to issue an appropriate Office Action addressing this issue. We note, however, that any action on the merits should provide appellant with an appropriate time for a response.

B. Are all claims on appeal disposed of by affirming this rejection?

Appellant appears to be of the impression that this rejection, which reaches all claims on appeal, should be affirmed. Accordingly, if the examiner had not withdrawn the rejection from this record, affirming the rejection would have disposed of all claims on appeal. Under such a circumstance, this panel is unaware of any rule of law that would compel it to reach the remaining issues on appeal.

In the event of further prosecution, if appellant believes that a terminal disclaimer is necessary to overcome a rejection, we encourage appellant to file such a disclaimer in a timely manner. Cf. In re Deters, 515 F.2d 1152, 1157, 185 USPQ 644, 648 (CCPA 1975) ("Since no terminal disclaimer was timely filed, we sustain ... [the obviousness-type double patenting] rejection."); In re Jursich, 410 F.2d 803, 807, 161 USPQ 675 (CCPA 1969), footnotes and citations omitted, ("The record shows that appellants' assignee filed a terminal disclaimer in the Patent Office after the board decision which the board refused to consider because it was not timely presented or considered by the examiner. Appellants assign error in that action by the board, arguing that the terminal disclaimer 'eliminated the double patenting issue in the present case.' However accurate that statement may be, we cannot consider the disclaimer here....").

3. The rejection of claims 26 and 28 under 35 U.S.C. 112, second paragraph:

We recognize appellant's statement (Brief page 8), "the examiner has objected to claims 26 and 28 due to an informality in the claim language. Paper 8, page 13. This informality has been corrected by an amendment filed concurrently herewith." However, as we understand the record, these amendments have not been entered. See Answer, page 2, paragraph 4; and Brief, page 2 "[t]hese amendments have not been entered." Thus, the "informality" has not been corrected by amendment. The rejection, however, was not repeated in the Answer and therefore appears to have been withdrawn as a matter of standard procedure. Paperless Accounting.

Accordingly, we remand the application to the examiner to determine whether the rejection of claims 26 and 28 under 35 U.S.C. 112, second paragraph should have been withdrawn from the record. In the event the examiner finds that this rejection should not have been withdrawn, we encourage the examiner to issue an appropriate Office Action addressing this issue. We note, however, that any action on the merits should provide appellant with an appropriate time for a response.

OTHER ISSUES

While we take no action on the merits of this appeal, we make the following observations in an effort to advance prosecution. The examiner finds (Answer, page 4), appellant's specification discloses (page 9),

"the process of the present invention, sometimes called de novo speciation, can be divided into the following stages:

- (I) Culturing virally-infected eukaryotic cells under low oxygen conditions to produce a bacterium containing a eukaryotic and/or viral gene; and
- (II) Selecting and replicating at least one such bacterium."

According to the examiner (Answer, page 5), "[a]pplicant is calling for the de novo 'creation' of a new species and/or the 'creation of a life form', i.e., the bacterium, from eukaryotes without the introduction of bacterial genes or the bacteria themselves." Stated differently, the examiner finds (id.), "[a]pplicant is calling for the 'spontaneous' production of a new bacterium without the introduction of the bacteria or the bacterial genome."

In our opinion, there can be no dispute that “prokaryotes and eukaryotes constitute separate and distinct life forms having many differences in structure and function.” Answer, page 5. There can also be no dispute “that Louis Pasteur effectively disproved the principles of spontaneous generation at the end of the last century....” Id.; Accord Reply Brief, page 2, “‘spontaneous generation’ as that term is used in biology in reference to the theory that the [e]xaminer correctly points out was refuted by Louis Pasteur over a century ago.”

According to appellant (Brief, page 8), the dispute on this record is just a matter of “semantics”¹. Backing away from the express language of claim 1, appellant explains (Brief, bridging sentence, pages 8-9, emphasis added),

[w]hat the applicant has [really] invented is a method that allows one to take cultured retrovirally-infected eukaryotic cells, uncontaminated with bacteria, subject them to a series of specific culturing conditions, and obtain at the end a culture of what, from a morphological point of view, can only be described as ‘bacteria,’....

This is not, however, the invention of claim 1. See e.g., Answer, page 14, “[a]ll claims are drawn to the methods of producing bacteria containing a eukaryotic and/or viral gene not ‘cells that morphologically can only be described as bacteria wherein said cells contain intact eukaryotic and/or viral genes.’”

¹ We remind appellant, “[t]he name of the game is the claim.” *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). Semantic arguments regarding the scope of the claimed invention should have been resolved during prosecution. As set forth in *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) it is:

during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. ... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

While apparently stepping away from the “morphological” argument, and perhaps towards the examiner’s position, appellant asserts (Reply Brief, page 2), “the term ‘producing’ as used in the present claims ... refers to the undeniable fact that one starts the process with cells identifiable as belonging or coming from one species (a eukaryotic cell), and ends up with cells that are identifiable as belonging to another (a bacterium).” Stated differently, “de novo speciation,” see infra. With regard to the term “identifiable” we note that according to the Steuer Declaration (paragraph 4), notwithstanding rigorously sterile conditions, the claimed method resulted in the “production” of bacteria identified as B. licheniformis. We note, however, as does the examiner (Answer, page 14), “no claim recites the limitation that the eukaryotic cultures need to be ‘uncontaminated by bacteria.’”

Nevertheless, declarant appears to go beyond appellant’s assertion (Brief, bridging sentence, pages 8-9), that from a morphological point of view, the cells can only be described as bacteria to identifying the cells produced by the method as a particular type of bacteria, specifically, B. licheniformis. What appears to be missing, however, from the Steuer Declaration, is any indication that the B. licheniformis, produced by the method set forth in appellant’s claim, “contains a eukaryotic and/or viral gene,” as is required by the claimed invention. As set forth in appellant’s Brief (page 19),

since the bacteria are formed from the eukaryotic cells. A person of ordinary skill in the art would recognize that any eukaryotic genes present in bacteria produced by the claimed methods would be intact, stable and integrated in the genome, because that would be their condition prior to performance of the claimed methods. In

any event, methods for detecting, analyzing, evaluating and characterizing genes are routine procedures for the person of ordinary skill in the art.

Given the admitted routine nature of the methods for detecting, analyzing, evaluating and characterizing genes, it is unclear why the B. licheniformis “produced”² by declarant following methodology set forth in appellant’s claimed invention was not screened for the presence of a eukaryotic and/or viral gene as is required by the claimed invention. See e.g., Answer, page 15.

We also recognize the examiner’s assertion (Answer, page 8), “it is well known in the art that strains of bacteria that were recovered after the claimed method are common cell culture contaminants.” We are, however, unable to identify any evidence upon which the examiner relies upon to support this assertion. Furthermore, we find no evidence on this record to explain why these “strains of bacteria” would contaminate cells cultured under sterile conditions, and even if they did why these “strains of bacteria” would contain a eukaryotic and/or viral gene as required by appellant’s claimed invention.

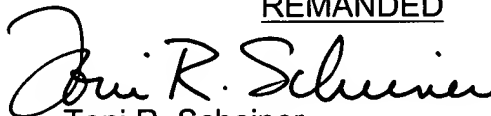
In this regard, we remind the examiner that findings of fact and conclusion of law by the USPTO must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A),(E), 1994. Dickinson v. Zurko, 527 US 150, 158, 119 S. Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Our reviewing court

² According to declarant (Steuer Declaration, page 6), the B. Licheniformis bacteria isolated as described in the Final Report did not originate as contaminants in the starting cell culture. Further it is my professional opinion that environmental contamination during the cell culturing processes is highly unlikely due to the procedures and practices employed in the performance of the study.

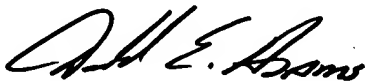
has held that findings of fact must be supported by substantial evidence within the record. In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000) (“because our review of the board’s decision is confined to the factual record compiled by the board ... the ‘substantial evidence’ standard is appropriate for our review of board fact findings, see 5 U.S.C. § 706(2)(E).”). See also In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002) (a board decision denying patent must be founded on necessary findings and must provide an administrative record showing the evidence which the findings are based; the board must assure the requisite findings are made, based on evidence of record).

For the foregoing reasons, prior to any further action on the merits, we encourage both the examiner and appellant to take a step back, and reconsider the administrative record to determine if the arguments of record are supported by an adequate evidentiary basis on this record.

REMANDED


Toni R. Scheiner

Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

)
)
)
)
) BOARD OF PATENT
)
) APPEALS AND
) INTERFERENCES
)
)
)

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON DC 20005